

RESPONSE

In the Claims

1. Please cancel claims 49, 50, 53, and 54 without prejudice.

2. Claims 4-9, 11, 13-16, 18-26, 28-32, 34-48, 51, 52, and 55-66 are pending in the Application.

3. Claims 4-9, 11, 13-16, 18-26, 28-32, 34-48, 51, 52, and 55-60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Int'l Pub. No. WO 98/03267 to Coffee ("Coffee") in view of U.S. Pat. No. 4,197,289 to Sturzenegger *et al.* ("Sturzenegger"). The Examiner states that Coffee discloses processes and apparatus for forming material by electrohydrodynamic comminution capable of producing various solid and partially solid forms, such as fibers, etc., which forms may also contain a biologically active ingredient ("AI"). In his analysis, the Examiner contends that "[o]ne of ordinary skill in the art would have been motivated to combine the Coffee and Sturzenegger references in order to devise a continuous method of manufacturing dosage forms . . . with a reasonable expectation of success." Finally, the Examiner disagrees with Applicant's assessment of Sturzenegger.² The Examiner goes on to assert that, with respect to Sturzenegger, "the disclosed product is described very simply as a web, and [in his view], holes and voids will be inherent in such a product" and that "[i]t is the position of the examiner that one of ordinary skill would not reasonably view such an inherent property as a defect to be avoided." Examiner's Office Action, August 24, 2004.

4. Applicant would like to first address the use of the term "web". As clearly stated in Sturzenegger, "[t]he webs utilized in accordance with the invention are formed by processes conventional in the arts, e.g. the paper-making and film making industries" and are "cast on a appropriate substrate" or formed by "extrusion". Sturzenegger at 10:4-17.

² Applicant has characterized Sturzenegger variously as "a method for forming solid dosage forms from a web . . . the web . . . formed using standard techniques from the paper- or film-forming industries", "a continuous sheet or membrane, *not an open web*", and treating "holes in the web" as *defects*. (Emphases added.) Applicant's Amendment, July 26, 2004. Applicant's assessment has been taken directly from Sturzenegger.

Applicant's web is open and porous. Specification at Fig. 9 and accompanying text. In usage, the term "web" is defined, first, as "[a] thin metal plate or strip" or "[a] large continuous roll or paper". Webster's II New College Dictionary 1252 (1995). This is clearly the use of the term "web" intended by Sturzenegger. Not only does Sturzenegger refer to the paper-making industry, it mentions such "webs" are formed by casting or extrusion. Neither of these process would produce Applicant's "web". In another usage, the term "web" is defined as "[a]n interlacing of materials that forms a latticed or woven structure" and "[a] structure of threadlike filaments" Id. at 1252. This is just as clearly the use of the term "web" intended by Applicant. Thus, the Examiner's comparison of the web in Sturzenegger with Applicant's web is an oversimplification. It is black letter patent law that the claims are read in light of the specification. See, e.g., Robert L. Harmon, *Patents and the Federal Circuit* 205 (Fourth Ed.), discussing *Markman v. Westview Instr., Inc.* 52 F.3d 967 (Fed. Cir. 1995) ("[T]he written description of the patent may act as a sort of dictionary, which explains the invention and may define terms used in the claims.")

5. Finally, the Examiner has stated that "holes and voids will be inherent in such a product [as the dosage form taught in Sturzenegger]" and that "one of ordinary skill would not reasonably view such an inherent property as a defect or as property to be avoided." Office Action at 6. Applicant respectfully directs the Examiner to the Sturzenegger disclosure. "As the web is produced . . . it undergoes an inspection step . . . to ensure the integrity of the web" At 10:49-53. "Holes, blemishes, and physical integrity of the web may be evaluated and quantified" At 11:23-25. "The electrical output [of the inspection apparatus] is used to count the number of defects and determine their size and distribution" At 11:34-36. From these quotes, it is apparent that one of ordinary skill *would* reasonably view such as a defect to be avoided. The very fact that Sturzenegger teaches such lengths to inspect for such "defects" attests to the importance of avoiding such.

6. It is the position of the Examiner that "one of ordinary skill in the art could combine the collective disclosures of the prior art with a reasonable expectation of success. In *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991), the Federal Circuit articulated a two-part test for determining proper combination of references for the purpose of an obviousness rejection under

35 U.S.C. § 103(a). First, the prior art would have suggested the claimed composition, device, or process. And second, the prior art would have revealed a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be found in the prior art. Based upon the above discussion, Applicant contends that neither prong of this test is satisfied in the instant case. Sturzenegger was looking for a process that would produce a solid dosage tablet that would minimize or eliminate holes and other defects. Coffee, oppositely, teaches a highly porous open web which has, as one of its primary features, holes and an open structure. Thus, there is no suggestion. Second, not only is there a lack of a reasonable expectation of success with the method of Coffee, the method of Coffee simply would not work for Sturzenegger.

7. In conclusion, Applicant respectfully asserts the Examiner has improperly cited Coffee in view of Sturzenegger and that such combination of references is an improper and ineffective foundation upon which to support an obviousness rejection under 35 U.S.C. § 103(a).

8. Notwithstanding, in the abovementioned telephonic interview it was agreed the obviousness rejection would be withdrawn if the claims were amended to clarify the type of web. Accordingly, independent claims 19, 30, 34, and 55, the only pending independent claims in the case, now include a "fibrous porous" web or mat and withdrawal of the rejection is respectfully requested. Support for these amendments is found in the Abstract, in the Specification at 9:10, and Fig. 9 and entry by the Examiner is respectfully requested. In light of the foregoing, Applicant respectfully submits that the rejection under 35 U.S.C. § 103(a) is no longer applicable to the claims currently pending in the Application.

9. During the telephonic interview, it was suggested by the Examiner and his supervisor that claim 19 be canceled, but no agreement was reached. Claim 19 now recites a support surface comprising at least one recess oppositely charged from the charged fiber or fibrils. Support for this amendment is found in the Specification at 21:22-22:11 and Fig. 5 and entry by the Examiner is respectfully requested.

10. Claims 61-66 are new. Support for these new claims is found throughout the Specification and entry by the Examiner is respectfully requested. New claims 61-66 depend from arguably allowable independent claims.

Closure

1. Previously, fees were paid for a total of 52 claims and 4 independent claims. As submitted herewith, a total of 54 claims and 4 independent claims are remaining with the Application. Thus, additional claim-related fees under 37 C.F.R. § 1.16(i) of \$50.00 (2 claims*\$25) are due.

2. This is a request for a three-month extension of time to respond to the Office Action. A period for response was set to expire November 24, 2004. Thus, pursuant to 37 C.F.R. §§ 1.17(a)(3) and 1.27(a)(3) an extension-related fee of \$510.00 is due.

3. Applicant encloses herewith a credit card authorization form PTO-2038 for \$560.00 for the abovementioned fees. Please charge any additional fees, or credit any overpayments in connection with this Response to Applicant's undersigned counsel's Deposit Account 021266. A duplicate copy of this authorization is also enclosed.

4. The undersigned attorney for Applicant has made a good faith effort to meet the concerns expressed by the Examiner in the Office Action. If the Examiner still has some issues with the Application, and has any suggestions as to how to address them, the Examiner is invited to call the attorney for Applicant at the phone number below, so that those issues may be resolved.

5. Applicant submits that this Application is now in condition for further favorable consideration, culminating in allowance. Such action is respectfully requested.

Respectfully submitted,



William B. Richards, Esq.
Reg. No. 44,301
Attorney for Applicants

Battelle Memorial Institute
505 King Avenue
Columbus, OH 43201
Phone: 614/424-5612
Fax: 614/424-3864

E-mail: richardsw@battelle.org
Customer Number: 24116